DRAFT ISSUE SUMMARIES

Transmissible Spongiform Encephalopathies
Advisory Committee Meeting

18-19 January 2000

Issue 4.

Potential Exposure of Blood Donors to Various TSE Agents of Animals

The FDA has received inquiries expressing concern about the potential transmissibility of various TSEs of animals. No human TSE except for vCJD has been convincingly attributed to infection with an animal TSE agent. Nonetheless, as part of its commitment to ensure the safest possible blood supply, the FDA asks the TSEAC to consider whether exposure to any of the animal TSE agents known to be present in the USA or that might accidentally be introduced into the USA might pose sufficient risk as to compromise the suitability of blood donors. The following sources of potential exposure of blood donors to animal TSE agents within the USA will be discussed:

- Products derived from deer and elk with chronic wasting disease
- Products derived from sheep and goats in or originating from BSE countries including imported sheep and their descendants with undifferentiated TSE ("Vermont" sheep)
- Ruminant-derived materials as components in dietary supplements

Reference

Norton SA. Raw animal tissues and dietary supplements. New Engl J Med 2000;343:304-305

Charge

The TSEAC should consider whether the agent of any of the animal TSEs reviewed is likely to infect humans exposed to the animals or to their products and whether the probability that blood donors have been infected is sufficient to warrant the FDA recommending their deferral.

Questions

1. Should the FDA be sufficiently concerned about the suitability of any blood donors potentially exposed to TSE agents of animals to consider recommending deferral?

2. If so, which animal TSE agents present in the USA, types of product and intensity of exposure should be of concern?